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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------------------|---------------------|------------------|
| 10/049,702 | 04/15/2002 | Camilo Anthony Leo Selwyn Colaco | 8830-24 | 7592 |
| 23973 | 7590 | 05/28/2008 | EXAMINER | |
| DRINKER BIDDLE & REATH | | | DUFFY, PATRICIA ANN | |
| ATTN: INTELLECTUAL PROPERTY GROUP | | | | |
| ONE LOGAN SQUARE | | | ART UNIT | PAPER NUMBER |
| 18TH AND CHERRY STREETS | | | | 1645 |
| PHILADELPHIA, PA 19103-6996 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| | | 05/28/2008 PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|--------------------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/049,702 | COLACO, CAMILO ANTHONY LEO SELWYN | |
| Examiner | | Art Unit | |
| Patricia A. Duffy | | 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 September 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 8-11 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 8-11 and 14-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

RESPONSE TO AMENDMENT

The amendment filed 9-27-07 has been entered into the record. Claims 8-11 and 14-16 are pending and are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The rejection of claims 8-11 and 14-16 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising a complex of heat shock proteins and antigenic peptides from cells infected with an intracellular bacteria, parasite or protozoa, it does not reasonably provide enablement for vaccines is withdrawn in view of the amendment to the claims.

The rejection of claims 9, 10, 11, 14 and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

The rejection of claims 8-11 and 14-16 under 35 USC 102(e) as being anticipated by Srivastava et al (US Patent 6,048,530) is withdrawn in view of Applicants amendments.

Rejections Maintained

Claims 8-11 and 14-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Srivastava et al (US Patent 6,048,530) for reasons made of record in the Office Action mailed 2-22-06 and reiterated herein.

Applicants' arguments have been considered but are not persuasive. Applicants argue that Example 5 indicates that the effect is not a dosage effect and that TNF-induced cells showed a 10-100 fold higher antibody titer than those immunized with constitutive SP's. This is not persuasive because the art teaches and expects that heat

induction of provides for increased levels of heat shock protein complexes as compared to the constitutive levels present in unstressed cells and therefore more immunogen. The example does not control for protein levels and does not indicate what level of purified complexes either SP or TNF-induced were injected. As such, Applicants still cannot rule out a dose effect of the induction of the heat shock protein and formation of more complexes. As previously set forth, the dose response nature of the immune response is well documented. Further, increased levels as expected in heat treated infected cells would be expected to be more immunogenic, by virtue that more are present in the composition. As to the TNF stimulation issue, Applicants still have not demonstrated any differences in the TNF - stressed or heat-stressed compositions as modified. In submitting evidence asserted to establish unobvious results, applicant has a burden of indicating how the examples representing the claimed invention relate to the prior art examples and how the latter represent the closest prior art, submitting evidence reasonably commensurate in scope with the claimed subject matter, establishing that the differences are in fact unexpected and unobvious and of statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318 (BPAI 1992).

The rejection is maintained.

Status of Claims

Claims 8-11 and 14-16 stand rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Primary Examiner

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